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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,151	01/15/2002	Jurgen Strube	2234/50345	6157

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,151

Applicant(s)

STRUBE ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments filed on December 30, 2003 is acknowledged. Claims 1-2 and 4-12 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6-7 recites that the amino acids are produced by adding distilled alcohol; this is indefinite since it is unclear how alcohol adds amino acids. Further clarification is requested.

Claim 9 recites that natural air adds amino acids, which is vague and indefinite. It is unclear how air adds amino acids to a composition. If this were the case, then any pharmaceutical composition exposed to air would be potentiated.

Claim 10 recites water as the potentiating agent, which is indefinite. The chemical structure of water is H₂O and this structure does not contain any amino acids. Claim 10 depends on claim 1 which clearly recites that the potentiating agent contains amino acids. Further clarification is requested.

Claim 11 recites lactose as the potentiating agent, which is indefinite. Lactose is a sugar and claim 11 depends on claim 1 that clearly recites that the potentiating agent contains amino acids. Further clarification is requested.

Response to Arguments

Applicant argues that under the accepted theories of homeopathic medicine, the amino acids present are impurities derived from air-borne or water-borne sources.

Applicant's arguments have been fully considered but they are not persuasive.

Although the examiner is not questioning the homeopathic theories or medicine, applicant's definitions of the instant terms is repugnant to the conventional, textbook definition and a skilled artisan would not readily ascertain the scope of the claims. For instance, air's composition is defined as 78.08% nitrogen, 20.9% oxygen, 0.93% argon, 0.033% carbon dioxide, 0.0018% neon, 0.00052% helium, 0.0001% krypton, and less than 5-ppm carbon monoxide. The examiner does not see the requisite "amino acids". If the applicant is claiming a terminology that is not conventional to the accepted terminology in the art, it must be defined in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This also extends to the applicant's terminology of water and alcohol. The conventional and accepted terminology does not include amino acids in the chemical structure. Lastly it should be noted that upon reading the specification, applicant states that distilled water or alcohol is not used since they are purified and do not contain the requisite amino acids. However, claim 6 recites utilizing distilled fruit alcohol. Therefore, the rejection of the claims as being indefinite is maintained. If applicant submits literature supporting the theories then the rejections will be reconsidered; however without evidence supporting such statements, the examiner relies on established scientific data.

Response to Arguments based on Prior Art Rejections

Applicant's arguments with respect have been considered but are moot in view of the new ground(s) of rejection necessitated by the Amendments filed. It should be noted that allowability of claim 8 is withdrawn based on amendments made to the previously allowable claim. The applicant has changed the word potentiating to potentising claiming that this word has a different scope and connotation in homeopathic medicine, said scope encompassing the process of successive steps of dilution (see page 8 of applicant's remarks) and thus the claims are drawn to a different method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 9, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al (5,603,915).

Nelson et al disclose a process for manufacturing homeopathic medicines by contacting the homeopathic medicine with a carrier solution (potentising agent) containing alcohol, water, seawater, brain hormone and biologically active enzymes. See abstract and examples. Further, Nelson discloses a method of preparing a homeopathic medicine with Nx potency by adding one part active and nine parts of the

carrier solution and dispersing the active in the solution. The solution is diluted to the required potency by repeating the step. See column 2, lines 42-67.

*It is the examiner's position that the extract inherently contains the instant amount of amino acids. The basis of inherency is that the base tincture contains various hormones and enzymes, which inherently contain amino acids and falls within instant range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (5,603,915).

Nelson et al disclose a process for manufacturing homeopathic medicines by contacting the homeopathic medicine with a carrier solution (potentising agent) containing alcohol, water, seawater, brain hormone and biologically active enzymes.

See abstract and examples. Nelson teaches the conventional use of water and alcohol as carrier solutions in homeopathic medicine. Further, Nelson discloses a method of preparing a homeopathic medicine with Nx potency by adding one part active and nine parts of the carrier solution and dispersing the active in the solution. The solution is diluted to the required potency by repeating the step. See column 2, lines 42-67.

Nelson et al do not specify the source of the alcohol.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to Nelson et al and his disclosed conventional homeopathic practices and utilize the desired alcohol. One would be motivated to do so since Nelson teaches the conventional practice of utilizing alcohol as the potentiating agent in homeopathic medicine. Although, the source of the alcohol is not specified, the source per se of the alcohol does not impute patentable difference to claims unless the applicant can provide unexpected results demonstrating that the source *itself* compared to other types of alcohol provides the requisite result. Furthermore, since the critical feature of the invention itself, i.e. the amino acids, are contained in the Nelson's potentiating medium, it is the examiner's position that the alcohol does not impute a patentable difference.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (5,603,915).

Nelson et al disclose a process for manufacturing homeopathic medicines by contacting the homeopathic medicine with a carrier solution (potentiating agent) containing alcohol, water, seawater, brain hormone and biologically active enzymes.

See abstract and examples. Nelson teaches the conventional use of water and alcohol as carrier solutions in homeopathic medicine. Further, Nelson discloses a method of preparing a homeopathic medicine with Nx potency by adding one part active and nine parts of the carrier solution and dispersing the active in the solution. The solution is diluted to the required potency by repeating the step. See column 2, lines 42-67.

Nelson does not teach the use of lactose in the carrier solution.

WO 97/29737 teaches combining allopathic substance with corresponding homeopathic substances. The compounds are homeopathically activated by diluting in a water-alcohol or alcohol-glycerin-water, lactose, or lactose-saccharose, or lactose-fructose-saccharose carrier. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Nelson et al and WO and utilize lactose in Nelson's base solution. One would be motivated to do so since WO teaches the conventional diluents and combinations of diluents utilized in homeopathic medicines, which includes water, alcohol, and various sugars such as lactose. It is deemed prima facie obvious to utilize diluents that are conventionally utilized in the given art, i.e. homeopathic art.

Miscellaneous Remarks

A translation of the foreign application should be submitted to provide support for the change in the terminology from potentiating to potentisating in reply to this action to avoid a new matter rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 6, 2004


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